MAY 1 6 2001

K010510
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510(k) Summary
As Required by 21 section 807.92 (c)

1-Submitter Name: A & A Medical, Inc.
2-Address: 9370 Industrial Trace
Alpharetta, GA 30004
3-Phone: (770) 343- 8400
4-Fax: (770) 343- 8985
5-Contact Person: Jihad Mansour
6-Date summary prepared: February 19th, 2001
7-Device Trade or Proprietary Name: Balloon Cannula
8-Device Common or usual name: Balloon Cannula
9-Device Classification Name: Laparoscope, Gynecologic and accessories
10-Substantial Equivalency is claimed against the following device:

- Balloon Cannula 15mm x 35mm-10/12mm (Model# ML1012D ZJ) (i.e., short) and 15mm x 55mm- 10/12mm (Model# ML1012LD ZJ) (i.e., long)

11-Description of the Device:

The device is to be used by physicians in hospitals
This device is a single use, disposable sterile cannula intended for minimally invasive laparoscopic surgery to provide access for operative and diagnostic instrumentation
Balloon cannula comprises of the following:

- Main body, made out of ABS hard plastic (low profile to increase instrument working length)
- Elliptical balloon to provide internal stabilization, made out of silicon
- Atraumatic surface disk to provide external stabilization, made out of rubber
- Built in flap reducer for easy exchange of instruments, made out of rubber

It is available in two versions:
R65-985 has an outer cylinder of 15mm (OD) and 35mm (Length) while R65-985-1 has an outer cylinder of 15mm (OD) and 55mm (Length). In both versions, an inner hole in the cylinder allows entry of 10-12mm instruments

12-Intended use of the device:

This device is a single use, disposable sterile cannula intended for minimally invasive laparoscopic surgery to provide access for operative and diagnostic instrumentation

13-Safety and Effectiveness of the device:

This device (**Balloon Cannula**) is safe and effective as the other predicate device cited above. This is better expressed in the tabulated comparison (Paragraph 14 below)

(REVISED 5/3/01)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that **Balloon Cannula** is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached.

FDA file reference number	510k 960810
Attachments inside notification submission file	REFER TO TABLE ON PAGE 11 OF 12 FOR DETAILS
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Identical
Materials	Identical
Performance	Identical
Sterility	Similar (Ethylene Oxide instead of Gamma irradiation)
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical (not applicable)
Thermal safety	Identical (not applicable)
Radiation safety	Identical (not applicable)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 6 2001

Jihad Mansour, MSQA, BE, LA, RAC
Quality and Regulatory Manager
A & A Medical, Inc.
9370 Industrial Trace
ALPHARETTA GA 30004

Re: K010510
Balloon Cannula, (Laparoscopic blunt trocar/sleeve) Short, Model R65-985
Balloon Cannula, (Laparoscopic blunt trocar/sleeve) Long, Model R65-985-1
Dated: February 19, 2001
Received: February 21, 2001
Regulatory Class: II
21 CFR §884.1720/Procode: 85 HET

Dear Mr. Mansour:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K010510

Device Name: Balloon Cannula (laparoscopic blunt trocar/sleeve)

Indications For Use:

This Balloon Cannula (laparoscopic blunt trocar/sleeve) is indicated for use in minimally invasive laparoscopic surgery to provide access for operative and diagnostic instrumentation

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Jegerman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010510